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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/784,488

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EXAMINER

SOROUGH, LAYLA

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/784,488	Applicant(s) GALANTE ET AL.	
	Examiner LAYLA SOROUGH	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 15, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-9,11,13,16,20,21,61,63,66 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,7-9,11,13,16,20,21,61,63,66 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed February 15, 2008 presents remarks and arguments submitted to the office action mailed November 15, 2007 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of 1, 5, 7-9, 11, 13, 16, 20, 21, 61, 63 and 66-70 over Banowski et al. (WO 99/23998 as translated by US 6,569,438) in view of Swaile et al. (US 5,968,489) is persuasive in view of the amendments made to the claims. Therefore, the rejection is herewith withdrawn.

Claims 1, 5, 7-9, 11, 13, 16, 20, 21, 61, 63 and 66-67 are pending.

In view of Applicant's amendments to the claims, the following new rejections are made:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7, 9, and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Banowski et al. (WO 99/23998 as translated by US 6,569,438).

Banowski et al. teach dermatological stick formulations comprising antiperspirant agents such as sodium aluminium chlorohydroxylactate (See US 6,569,438 @ col. 3, lines 5-23) and two or more separate, differently composed gel phases, wherein the phases contain deodorant or perspiration-inhibiting actives. See US 6,569,438 @ col. 1, lines 47-60; col. 3, lines 1-22. The phases may differ in color and/or content of polymer

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powder and the active ingredients. See col. 4, lines 38-42. The compositions Banowski et al. contain water, gelling agents, waxes, polyhydric alcohols and other conventional cosmetic agents; for example magnesium stearate. See col. 2, lines 3-33; Examples. The core phase of the composition may be cylindrical or "be arranged parallel to the longitudinal axis of the stick". See col. 5, lines 10-18. With respect to the claimed limitation "one portion is firmer than, and provides support for the other portion", it is noted that some compositions exemplified by Banowski et al. contain different amount of waxes in core part ("K") and shell or jacket part ("H"), which would result in different firmness of the compositions. See, for example, col. 10, lines 50-60 (K9 and H6 composition).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 13, 16, 20, 21, 61, 63 and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banowski et al. (WO 99/23998 as translated by US 6,569,438) as applied to claims 1, 5, 7, 9, and 11 in view of Swaile et al. (US 5,968,489), all of record.

Banowski et al. does not teach the hydrophilic vehicle in the percentage of the instant claims.

Swaile teaches hydrophilic vehicles in the percentage claimed (see Examples). Also, antiperspirant actives (i.e. aluminum and zirconium salts) are well known and widely used in the art of antiperspirant compositions, as taught by Swaile et al. (col. 9-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of Banowski et al.'s compound by routine experimentation (see 2144.05 11). The motivation to optimize the dose range of the Banowski et al.'s final formulation is because one would have had a reasonable expectation of success in achieving the safest clinical outcome.

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007). In *KSR*, the Supreme Court emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art." *Id.* at 1739, 82 USPQ2d at 1395. In the instant case, all the claimed element are found in the prior art as discussed above and using the amount of hydrophilic vehicle and antiperspirant salts of Swaile et al. in the deodorant/antiperspirant compositions of Banowski et al. is nothing more than "predictable use of prior art elements according to their established functions." *Id.* at 1740, 82 USPQ2d at 1396.

Response to Arguments

Applicant's arguments filed February 15, 2008 have been fully considered. The response to the arguments is as discussed below:

Applicant's arguments with respect to Banowski et al. and Swaile et al. have been considered but are moot in view of the new ground(s) of rejection.

However, in response to Applicant's argument that it is difficult to prepare a two portion composition as described in the methods of Banowski et al. is not persuasive. The Applicant is arguing a product-by-process. It is well settled in patent law that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP § 2123. The court in In re Thorpe held, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Additionally, in order to overcome an obviousness rejection Applicant must provide a 132 Declaration with a comparison of the invention and the prior art relied upon. Unless comparison is made with disclosure identical (not similar) with that of the reference, affidavits or declarations comparing applicant's results with those of the prior art have no probative value.

The arguments are not persuasive and the rejection is made **FINAL**.

Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617